ClinPhone's comments on draft guidance for industry entitled "Computerized Systems Used In Clinical Trials" dated 29th December 2004.

Lines 54-57 addresses the coverage of the Guidance document be limited to collection of clinical trials data by clinical sites, sponsors, contract research organizations, and data management centers. Is there discussion about expanding the guidance to apply to all systems which collect, send or receive clinical data from ANY third party system?

Line 95 assumes direct computer system data entry and source, but there is no account made for the electronic Patient Reported Outcomes (ePRO) definition of Transient Data Collection, as the label implies, is a state of data that is not intended to be permanent. Transient data may be sent to a printer, processed further by the system, or transmitted to another computer system. It may be used internally by the system without ever being permanently stored, or it could ultimately become part of an electronic record.

Line 98, section 7 does not address how to capture audit trial information due to system problems or natural disasters?

Line 102 states an audit trial that is electronic or consists of OTHER physical, logical, or procedural security measures.... The use of the word "other" audit trial implies it is acceptable to capture audit trials by non-electronic means in contradiction of 21 CFR Part 11 preamble 73, page 13447. Will this lead to an easing of the regulations on how audit trials are captured?

Line 109 and Line 214 recommend that audit trials capture "why changes were made to the electronic record. This contradicts statements made in 21 CFR Part 11 preamble, section XVI.D paragraph five, and page 13464, which excludes the recording in audit trials the reason why records were changed.

Line 196 recommends that clinical investigators retain either the original or a certified copy of any documentation created to track electronic records activities. This guidance appears to put the burden on the investigative sites for all computer systems. Should this be applied to investigator sites where the system is owned by the sponsor or contract research organization that would hold the data on behalf of the investigator?

Lines 256-259 recommends features that can be incorporated into the computerized system. One feature not specified is the use of drop down boxes with predefined data fields. Would this be an acceptable feature to be incorporated in the computerized system?

Lines 307-308 does not take into account other organizations (i.e. CROs), where the information collected (i.e. patient diaries or interactive voice response (IVR) system data) does not directly apply to the investigator site. What value does it add for clinical sites to collect this information on other sites and/or organizations?

Lines 329-331 recommends that clinical sites retain an overall description of the computerized systems and the relationships among hardware, software, and physical environment. Would this still apply to clinical sites where the computer system resides and maintained by the sponsor or CRO, but accessed via alternate method (i.e. telephone)?

Line 385 assumes for COTS software is already validated. Should this assumption that most off the shelf software have completed design level validation be addressed?

Line 388 suggests that the sponsor or CRO conduct on-site vendor audit. As this has not been recommended in the past, does this relate to a new regulation?

Line 401 states design specification. Should this be functional requirements, which are usually not available in COTS purchases?

Line 416 addresses written procedures be put in place to ensure changes to the computerized system such as performance patches. Would this include things like Service Patch 2 for Microsoft XP?

Line 432 recommends that measures be put in place to ensure that versions of software used are versions that are stated in the systems documentation. This statement implies that the validation packages would need to be updated every time a supporting piece of software is implemented. Should this be clarified to allow organizations to manage and document the software and versions as appropriate to the business?

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